

REMARKS

Claims 16-30 are pending.

Applicants thank the Examiner for granting an interview with Applicants' representative on August 15, 2003. At the interview, the patentability of the pending claims was discussed.

Claims 16-30 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the teachings of U.S. Patent No. 5,484,601 to O'Leary et al. ("O'Leary"), U.S. Patent No. 5,385,887 to Yim et al. ("Yim") and WO 98/40113 ("Wironen"). Claims 16 and 27 are independent.

Applicants have discovered a bone graft substitute composition including calcium sulfate, demineralized bone matrix, cancellous bone, a plasticizing substance, and a mixing solution. See independent claims 16 and 27.

In formulating the rejection, the Examiner has picked calcium sulfate from Yim, picked demineralized bone matrix, a plasticizing substance, and a mixing solution from O'Leary, and picked cancellous bone from Wironen. There is no motivation to combine these features of Yim, O'Leary and Wironen. Indeed, obviousness cannot be established simply by stitching together pieces of prior art using the patent as a template. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cir. 1985); see also *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 873 (Fed. Cir. 1985) (denouncing courts' tendency to depart from proper standard of nonobviousness "to the tempting but forbidden zone of hindsight."); *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988) ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."); *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999) ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."). The cited references must provide some suggestion, motivation, or teaching for combining known components. See *Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc.*, 21 F.3d 1068, 1072, 30 USPQ2d 1377, 1379 (Fed. Cir. 1994) ("When the patented invention is made by combining known components to achieve a new system, the prior art must provide a suggestion or motivation to make such a combination."); *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340 (Fed. Cir. 2000). The requisite motivation to combine the references has not been provided. Thus, the Examiner has not presented a *prima facie* case of obviousness.

Here, the fact that the components could be removed from the other compositions and combined to obtain the claimed compositions is not a sufficient basis for obviousness. There

must be some suggestion in Yim, O'Leary or Wironen to form the specific combination of components included in claim 16 and 27. Second, while the Examiner claimed to have considered the references as a whole, the Examiner has actually ignored aspects of the references that suggest away from the Examiner's combination. Indeed, if the references were taken as a whole, as suggested by the Examiner, then a person skilled in the art would not have been motivated to combine the references.

For example, a person skilled in the art reading Wironen would be discouraged from looking to O'Leary. Wironen expressly characterizes O'Leary as being "a non-cross-linkable composition" (page 3, lines 22-23), which contrasts with Wironen's explicit requirement of a composition being "cross-linkable" (page 5, line 25). Thus, taken as a whole, a person skilled in the art reading Wironen would not be motivated to look to O'Leary, let alone combine the teachings of O'Leary with the teachings of Wironen.

With regard to combining Wironen with Yim, Wironen discloses using a gelatin as a carrier that has the ability to thermally cross-link (page 5, line 25). But neither Wironen nor Yim discloses or suggests that calcium sulfate is a carrier that has the ability to thermally cross-link. Without such a teaching, there is no suggestion or motivation in Wironen or Yim to combine calcium sulfate with the cancellous bone of Wironen. Thus, there a person of ordinary skill in the art would not have been motivated by the teachings of Wironen or Yim to form a composition of claim 16 or claim 27. Because O'Leary teaches compositions including demineralized bone, and does not teach or suggest compositions that include calcium sulfate or cross-linking, a person of ordinary skill would not have been motivated to combine any teaching of O'Leary with the teachings of Wironen or Yim. Thus, in the absence of hindsight, there is no motivation to combine the teachings of O'Leary, Wironen and Yim.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.


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Enclosed is a check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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